

REMARKS

An Office Action was mailed on June 27, 2007. Claims 1-38 are pending in the application, with claims 1-31 having been withdrawn as drawn to a non-elected invention. Claims 32-38 are rejected under 35 USC § 103 and on the ground of obviousness-type double patenting.

Applicants respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks below.

The Amendments to the Claims

Without prejudice to Applicants' rights to present claims of equal scope in a timely filed continuing application, to expedite prosecution and issuance of the application, Applicants have amended claims 32-38 and presented new claim 39. The amended claims and the new claim are supported by the present specification. See, *e.g.*, Paragraphs [0004], [0006], [0084], [0103], [0122], and U.S. provisional patent application Serial No. 60/429,404, incorporated by reference in the present application in its entirety, at page 3, lines 13-27.

The amendments to the claims do not introduce new matter. Applicants respectfully submit that the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to enter the amendments to the claims and allow all amended claims.

Claim Rejections Under 35 USC § 103

Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,891,885 to Caruso (Caruso).

The Examiner states that Caruso teaches "methods and compositions for the treatment of migraine headaches. Caruso teaches that preferred compositions include an anti-migraine agent in combination with a NMDA receptor blocker. Caruso teaches that compounds that also assist in blocking the consequences of NMDA receptor activation, and that are thus also suitable for use in the anti-migraine composition in addition to or in place of the NMDA receptor blocker include phenothiazines, such as chlorpromazine and prochlorperazine." Office Action at 3 (citations omitted). Thus, the Examiner concludes that Caruso teaches providing the antipsychotic phenothiazine compounds recited in the present claims for the treatment of

headache.

As amended, claim 32 recites a kit for the treatment of headache “comprising a composition comprising a dose of less than 9 mg prochlorperazine and a device for delivering the composition to a patient.” Caruso does not teach or suggest a composition comprising a dose of less than 9 mg prochlorperazine.

As described in the present specification, the inventors found that a low dose of prochlorperazine is effective in treating headache pain, particularly that associated with migraine. See Example 3; Figs. 3 & 4. Migraine headache severity was effectively reduced by administration of a 5 mg dosage of prochlorperazine and this was more effective than the 10 mg dose. See Paragraph [0151]. The inventors also noted “remarkable advantages” of using low dose prochlorperazine to achieve pain free patients. See Paragraphs [0153]-[0155].

The Examiner states that “Caruso teaches that the potentiating agent must be present in an amount that potentiates the effectiveness of the anti-migraine drug.” Office Action at 5. However, Caruso provides no indication as to what that amount might be. In fact, Caruso states that it “depends to a large extent on the specific antimigraine drug being administered” and thus must be separately determined for each particular drug combination. Caruso, col. 5, lines 53-60. The Examiner states that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phenothiazine antipsychotic provided in the composition, according to the guidance provided by Caruso, to provide a composition having desired potentiation of the anti-migraine drug. Applicants submit that Caruso provides no such guidance. However, even if Caruso did provide such guidance, there is no basis to conclude that the amount of phenothiazine antipsychotic required to provide a “desired potentiation” of the anti-migraine drug would be “a dose of less than 9 mg prochlorperazine” as required by the claim.

Moreover, claim 33 requires that the composition “comprises prochlorperazine as the only active ingredient.” Caruso does not teach or suggest such a composition. All of the compositions described in Caruso comprise an anti-migraine drug in addition to the “potentiating agent.” Thus, even if prochlorperazine were used as a potentiating agent in the composition of Caruso, it would not be the only active ingredient.

Neither U.S. Patent No. 5,699,789 to Hendricks et al. (cited as disclosing “instructions for

use”) nor U.S. Patent No. 5,743,251 to Howell et al. (cited as disclosing “condensation aerosol”) cure these deficiencies of Caruso. Accordingly, the Office Action fails to establish a *prima facie* case of obviousness, as each and every element of the invention is not taught or disclosed by these references.

In light of the amendment to the claims and the above arguments, Applicants respectfully request withdrawal of the rejection of claims 32-36 over Caruso, claim 37 over Caruso in view of Hendricks et al., and claim 38 over Caruso in view of Howell et al.

Double Patenting

Claims 32-38 are provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 32-38 of U.S. Patent Application Serial No. 11/346,548 as published in U.S. Patent Application Publication No. 2006/0193788 to Hale et al. Office Action at 8-9. The present claims have been amended, *inter alia*, to recite a “device for delivering the composition to a patient” and “composition comprising a dose of less than 9 mg prochlorperazine.” As amended, Applicants submit that the present claims and the claims of copending U.S. patent application Serial No. 11/346,548 are not coextensive in scope.

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 27 of U.S. Patent No. 7,090,830 to Hale et al. The Examiner states that the present claims are obvious over the patented claim which is “drawn to a kit having a particular inhalation device and a drug, where the drug can be prochlorperazine.” Office Action at 9-10. The present claims have been amended, *inter alia*, to recite a “device for delivering the composition to a patient” and “composition comprising a dose of less than 9 mg prochlorperazine.” Accordingly, Applicants submit that the present claims are not obvious over the patented claim.

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-27 and 43-62 of U.S. Patent No. 7,078,020 to Rabinowitz et al. The Examiner states that the present claims are obvious over the patented claims which are “drawn to a kit having a particular inhalation device and a drug, where the drug

can be prochlorperazine.” Office Action at 10. The present claims have been amended, *inter alia*, to recite a “device for delivering the composition to a patient” and “composition comprising a dose of less than 9 mg prochlorperazine.” Accordingly, Applicants submit that the present claims are not obvious over the patented claims.

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/633,877, as published in U.S. Patent Application Publication No. 2007/0031340 to Hale et al. The Examiner states that the present claims are obvious over the patented claims which are “drawn to an article for aerosol delivery having a substrate suitable for vaporization of a drug for aerosol delivery, and a drug, where the drug can be prochlorperazine.” Office Action at 10-11. The present claims have been amended, *inter alia*, to recite a “device for delivering the composition to a patient” and “composition comprising a dose of less than 9 mg prochlorperazine.” Accordingly, Applicants submit that the present claims are not obvious over the published claim.

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/633,876, as published in U.S. Patent Application Publication No. 2007/0028916 to Hale et al. The Examiner states that the present claims are obvious over the patented claims which are “drawn to an assembly for aerosol delivery having a substrate suitable for vaporization of a drug for aerosol delivery, and a drug, where the drug can be prochlorperazine.” Office Action at 11. The present claims have been amended, *inter alia*, to recite a “device for delivering the composition to a patient” and “composition comprising a dose of less than 9 mg prochlorperazine.” Accordingly, Applicants submit that the present claims are not obvious over the published claim.

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 27 of copending Application No. 11/488,932, as published in U.S. Patent Application Publication No. 2006/0280692 to Rabinowitz et al. The Examiner states that the present claims are obvious over the patented claims which are “drawn to a kit for aerosol delivery having a device for dispensing an aerosol, and a coating of a drug for

dispensing, where the drug can be prochlorperazine.” Office Action at 12. The present claims have been amended, *inter alia*, to recite a “device for delivering the composition to a patient” and “composition comprising a dose of less than 9 mg prochlorperazine.” Accordingly, Applicants submit that the present claims are not obvious over the published claim.

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of co-pending Application No. 11/248,598, as published in U.S. Patent Application Publication No. 2006/0120962 to Rabinowitz et al. The Examiner states that the present claims are obvious over the patented claims which are “drawn to a particular type of inhalation device having a dosage of drug, where the drug can be prochlorperazine.” Office Action at 12-13. The present claims have been amended, *inter alia*, to recite a “device for delivering the composition to a patient” and “composition comprising a dose of less than 9 mg prochlorperazine.” Accordingly, Applicants submit that the present claims are not obvious over the published claim.

Conclusion

Applicants appreciate the Examiner’s careful and thorough review of the application and submit that the Examiner’s concerns have been addressed by the amendments and remarks above. Applicants accordingly request the Examiner to withdraw all rejections and allow the application. In the event the Examiner believes a telephonic discussion would expedite allowance, help to resolve outstanding issues or prosecution of the application, then the Examiner is invited to call the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to Deposit Account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to Deposit Account No. 19-5117.

Respectfully submitted,

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/Katherine Lobel-Rice/
Katherine Lobel-Rice, #58,079
Swanson & Bratschun, L.L.C.
8210 SouthPark Terrace
Littleton, Colorado 80120
303-268-0066 Telephone
303-268-0065 Facsimile

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